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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 35, lines 10 and 11, "the central portion" lacks antecedent basis.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 35 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Staskin et al. (6,612,977). Staskin et al. disclose, at least in figures 12A, 12B, and 16A an introducer needle including a first flat spatulated section (126), a straight portion (at 130) connected to a distal end of the first spatulated section, a curved portion (distal of 130) connected to a distal end of the straight portion, a second flat spatulated section (106'), and a flared section (54B) connected to a distal end of the curved portion and

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connected at its distal end (narrow end of 54b) to the first flat spatulated section, the flared section having a cross-sectional profile that covers a cross-sectional profile of the first spatulated section, where at least one flat spatulated section (106') has a tip and a constant width portion disposed between the tip and its central portion and an opening (116), where the first flat spatulated section, the flared section, the straight portion, the curved portion, and the second flat spatulated section are integrally formed (i.e., integrated together).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-4, 120-123, 125-128 and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (6,612,977) in view of Richmond (4,509,516).

Staskin et al. disclose the invention substantially as claimed. Staskin et al. disclose, at least in figures 1, 1A, 4, 12A, 12B, 16A-16D, and 18A-18E; a system including an

introducer needle (60A or 60B) having a first end (170) and a second end (170), each having a flattened portion (e.g., 126); a handle (64G) having a latch mechanism (198), an implant member (42) having an end and a connector (56B—see fig. 12B) joining an end of the implant member to the second end (58) of the introducer needle; where the connector includes a central portion (a hinge between 112' and 54B), a first arm (54B) pivotally connected to the central portion and having a first opening (116), and a second arm (112') pivotally mounted to the central portion and having a first projection (114); where the needle is curved (see fig. 16A) and symmetrical (about the longitudinal axis), where the flattened portion or tip (at 174) of the first end (of needle 60B) differs in size and shape or configuration from the flattened end of the second portion (170) or second flattened portion, and where the needle has a flared section (tapered portion of 170 as seen on the left side of fig. 16A) having a cross-sectional profile that is at least as large as the cross-sectional profile of the connector, where the needle has rounded tip, an arcuate shape, and a circular cross-section; where the needle has an assymetric shape (with respect to an axis in the middle of the needle and transverse to the longitudinal axis of the needle), where the implant member has a central portion (66 or 42 with respect to claim 131) having first and second ends and first and second arms connected respectively to the first and second ends, and where the first and second arms (48 and 50 with respect to claim 131 or end portions of 42 with respect to claims 126-128) have a plurality of openings arranged in a two-dimensional pattern (i.e., the mesh of 42 has a pattern). However, Staskin et al. do not disclose that the flattened portion of each end of the needle has an opening therethrough. Richmond teaches, at

least in col. 2, lines 67 to col. 3, line 4 and col. 4, lines 41-44 and 51-60; an introducer needle with an opening (18) at each end of the needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Richmond, to include an opening in each end of the needle of Staskin et al. Such a modification would allow the needle of Staskin et al. to receive an implant (absent a connector) or a suture and thread the implant or suture through a narrow opening between organs or tissues.

7. Claim 124 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (6,612,977) in view of Richmond (4,509,516), and further in view of Smith et al. (4,799,484). Staskin et al. in view of Richmond disclose the invention substantially as claimed, but do not disclose that a portion of the needle has an oval cross section. Smith et al. teach, in figures 5a and 5b and in col. 2, lines 19-26 and col. 3, line 58 to col. 4, line 14; a needle with a circular or an oval cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Smith et al., to modify at least a portion of the needle of Staskin et al. in view of Richmond, so that it has an oval cross section. Such a configuration would ease the needle's penetration and rotation in tissue or material where the needle is applied.

8. Claims 129 and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staskin et al. (6,612,977) in view of Richmond (4,509,516), and further in view of Gellman (6,755,781). Staskin et al. in view of Richmond disclose the invention substantially as claimed, but do not disclose, inter alia, an implant member with an elongated body and a support portion with a plurality of slits as claimed. Gellman

teaches, at least in figures 1-3, 6A, and 6B, a flexible, bioabsorbable implant member with an elongated body and a support portion with a plurality of slits (10) as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Gellman, to configure the implant member so that it is formed with a flexible material and a plurality of slits as claimed. Such an implant member would be strong and bioabsorbable, while the slits would allow tissue ingrowth into the implant member, where ingrown tissue would provide further buttressing for the implant member and the organs or tissues being supported by the implant member.

#### ***Response to Amendment***

9. Applicant's arguments with respect to claims 1-4, 35, 36, and 120-131 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

June 17, 2008